

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

TALTON, et al.

Application No.:

09/856,415

Examiner:

WARE, T.

DEC 0 5 2002

Date Filed:

May 18, 2001

Group:

1615

IEUM CENTER 1600/2900

For:

METHODS FOR PREPARING COATED DRUG PARTICLES AND PHARMACEUTICAL FORMULATIONS THEREOF

CERTIFICATE UNDER 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Commissioner for Patents, Mashington, D.C. 20231, on

11/26/22

Reg. No. 46,803

Neil R. Jetter

# TRANSMITTAL LETTER

Commissioner for Patents Washington, DC 20231

Sir:

Please find enclosed for filing the following:

Supplemental Information Disclosure Statement, with PTO-1449, and references;

Fee in the amount of \$180.00 authorized to be charged to

Deposit Account No. 50-0951; and

1 postcard. <u>X</u>

Please charge any underpayment or credit any overpayment to Deposit Account

No. 50-0951. This letter is submitted in duplicate.

Respectfully submitted,

Date: \_\_\_\_ 1//26/02

Gregory A. Nelson, Reg. No. 30,577

Neil R. Jetter, Reg. No. 46,803

**AKERMAN SENTERFITT** 

222 Lakeview Avenue, Suite 400

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West Palm Beach, FL 33402-3188

Telephone: (561) 653-5000

Docket No. 5853-186US

{WP095826;1}



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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, DC 20231

Sir:

Pursuant to the Duty to Disclose under 37 C.F.R. §1.56, the cited references on the accompanying PTO-1449 are hereby brought to the attention of the Examiner for independent evaluation based on 37 CFR § 1.97(c). The fee required under 37 CFR §1.17(p) is also included herewith. Copies of the references are enclosed.

The claimed invention is believed patentable over the enclosed references. This citation is intended to give the Examiner an opportunity to make an independent evaluation. These references are not admitted prior art and no representations are made regarding this information.

Date: 11/26/02

Respectfully submitted

Gregory A. Nelson, Reg. Mo. 30,577

Neil R. Jetter, Reg. No. 46,803

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12/04/2002 ADSMAN1 00000082 500951

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{WP095826;1}





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Sheet 1 of 4

Form PTO-1449
(Rev. 2-88)

INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

(Use several sheets if necessary)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
5853-186US

APPLICATION NO.
09/856,415

APPLICANT
TALTON, et al.

FILING DATE
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GROUP
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		U.S. PATENT	DOCUMENTS			
KAMINER'S INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,565,056	April 7, 1987	Leuenberger			
	4,848,673	July 18, 1989	Masuda et al.			
	5,242,706	September 7, 1993	Cotell, et al.			1
	5,288,528	February 22, 1994	Blanchet-Fincher			
	5,399,363	March 21, 1995	Liversidge et al.			
	5,399,636	March 21, 1995	Alt et al.	0		
	5,437,889	August 1, 1995	Jones			
	5,456,917	October 10, 1995	Wise et al.			
	5,466,468	November 14, 1995	Schneider et al.		•	
	5,489,449	February 6, 1996	Umeya et al.			
	5,536,508	July 16, 1996	Canal et al.			
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	5,580,579	December 3, 1996	Ruddy et al.			
	5,641,515	June 24, 1997	Ramtoola			
	5,641,745	June 24, 1997	Ramtoola			
	5,656,016	August 12, 1997	Ogden			
	5,693,340	December 2, 1997	Harth et al.			
	5,697,899	December 16, 1997	Hillman et al.			
	5,702,716	December 30, 1997	Dunn et al.			
	5,725,871	March 10, 1998	Illum			
	5,756,353	May 26, 1998	Debs	-		
	5,766,557	June 16, 1998	Luy et al.			
	5,770,219	June 23, 1998	Chiang et al.			
	5,779,708	July 14, 1998	Wu			
		FOREIGN PAT	ENT DOCUMENTS			
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
						YES NO
	OTHER	DOCUMENTS (Including A	Author, Title, Date, Pertine	ent Pages, Etc	c.)	

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Form PTO-1449 (Rev. 2-88) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE ATTY. DOCKET NO. 5853-186US

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GROUP 1615

(Use several sheets if necessary) U.S. PATENT DOCUMENTS FILING DATE IF APPROPRIATE CLASS SUBCLASS DOCUMENT NUMBER DATE NAME EXAMINER'S INITIAL 5,780,045 July 14, 1998 McQuinn et al. Venkateshwaran et al. 5,783,208 July 21, 1998 Sarubbi et al. August 11, 1998 5,792,451 Santini, Jr. et al. 5,979,898 August 25, 1998 5,804,212 September 8, 1998 Illum Kawamura 5,820,833 October 13, 1998 Li-Bovet et al. December 15, 1998 5,849,265 Tice et al. 5,814,344 September 29, 1998 5,922,306 July 13, 1999 Akehurst et al. Gordon December 14, 1999 6,001,336 McGill et al. February 15, 2000 6,025,036 June 13, 2000 Tapphorn et al. 6,074,135 Benoit et al. 6,087,003 July 11, 2000 Cairns et al. September 6, 1977 4,046,712 4,623,588 November 18, 1986 Nuwayser et al. FOREIGN PATENT DOCUMENTS COUNTRY SUBCLASS TRANSLATION DOCUMENT NUMBER CLASS YES NO DE DE 42 39 244 A1 21.11.92 WO 00/28969 25.05.00 **PCT** WO 90/02546 22.03.90 **PCT** OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Swinyard, E.A. "Analgesics and Antipyretics" Remington's Pharmaceutical Sciences, 15th Edition, Chapters 59, 88 and 89, pgs. 1035-1038 and 1570-1580 Banker and Rhodes, Eds, Modern Pharmaceutics, Marcel Dekker, Inc., New York, 19990 Hardy, et al. "Sustained Release Drug Delivery to the Lungs" Clin. Pharm. 2000 Jul: 39 (1): pgs. 1-4 Talton, et al. "Nano-Thin Coatings for Improved Lung Targeting of Glucocorticoid Dry Powders: In-Vitro and In-Vivo Characteristics" Respiratory Drug Deliver, VII, 2000, pgs. 67-74. Sato, et al. "Porous Biodegradable Microspheres for Controlled Drug Delivery. I. Assessment of Processing Conditions and Solvent Removal Techniques" Pharmaceutical Research, Vol. 5, No. 1, 1988, pgs. 21-30 Thies, C. "Microcapsules As Drug Delivery Devices" Critical Review in Biomedical Eng.", Vol. 8, Issue 4, 1982, pgs. 335-383 DATE CONSIDERED EXAMINER EXAMINER: Initial if a citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not

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Sheet 3 of 4

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE APPLICATION NO. ATTY. DOCKET NO orm PTO-1449 5853-186US 09/856,415 (Rev. 2-88) APPLICANT INFORMATION DISCLOSURE STATEMENT TALTON, et al. BY APPLICANT GROUP 1615 May 18, 2001 (Use several sheets if necessary) U.S. PATENT DOCUMENTS SUBCLASS FILING DATE
IF APPROPRIATE NAME CLASS DOCUMENT NUMBER DATE EXAMINER'S INITIAL FOREIGN PATENT DOCUMENTS SUBCLASS TRANSLATION COUNTRY CLASS DOCUMENT NUMBER OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Bourlais, et al. "Ophthalmic Drug Delivery Systems - Recent Advances" Progress in Retinal and Eye Research, Vol. 17, No. 1, 1998, pgs. Talton, J.D. "Pulmonary Targeting of Inhaled Glucocorticoid Dry Powders" Thesis, University of Florida, 1999, pgs. 1-135 Hausberger, et al. "Characterization of Biodegradable Poly(D, L-lactide-co-glycolide) Polymers and Microspheres" Journal of Pharmaceutical & Biomedical Analysis, Vol., 13, No. 6, 1995, pgs. 747-760 Phadke, et al. "Laser-Assisted Deposition of Preformed Mesoscopic System" Materials Science and Engineering, C5, 1988, pgs. 237-241 Pique, et al. "Growth of Organic Thin Films by the Matrix Assisted Pulsed Laser Evaporation (MAPLE) Technique" Thin Solid Films, 1999, pgs. 355-356 and 536-541 Fluidization (Grace and Matsen, eds., Plenum Press, NY, 1980) Agarwal, et al. "Laser Assisted Deposition of Supramolecular Organizates on Solid Surfaces" Materials Science and Engineering C6, Sciarra, et al. Chapters 15 and 16 from Modern Pharmaceutics, pgs. 605-671 Burton, et al. "Absorption of Corticosteriods from the Rat Lung" Steroids, Vol. 23, No. 5, 1974, pgs. 617-624 Conti, et al. "Use of Polylactic Acid for the Preparation of Microparticulate Drug Delivery Systems" J. Micorencapsulation, Vol. 9, No. 2, 1992, pgs. 153-166 Fielding, et al. "Factors Affecting the Release Rate of Terbutaline from Liposome Formulations After Intratracheal Instillation in the Guinea Pig" Pharmaceutical Research, Vol. 9, No. 2, 1992, pgs. 220-223 Glatt, "Multi-Purpose Fluid Bed Processing", Product Literature, 1988 Göpferich, et al. "Development and Characterization of Microencapsulated Microsphere" Pharmaceutical Research, Vol. 11, No. 11, 1994, pgs. 1568-1574 Herdan, G. "Small Particle Statistics" Second Edition, Butterworths, London, 1960 Hochhaus, G. "Pharmacokinetic/Pharmacodynamic Aspects of Aerosol Therapy Using Glucocorticoids as a Model" J. Clin. Pharmacol. 1997; 37 pgs. 881-882 Hochhaus, et al. "Assessmen of Glucocorticoid Lung Targeting by ex-Vivo Receptor Binding Studies in Rats" Pharmaceutical Research, Vol. 12, No. 1, 1995, pgs. 134-137 Kawashima, et al. "A New Powder Design Method to Improve Inhalation Efficiency of Pranlukast Hydrate Dry Powder Aerosols by Surface Modification with Hydroxypropylmethylcellulose Phthalate Nanospheres" Pharmaceutical Research, Vol. 15, No. 11, 1998, pgs. Kodas, et al. "Aerosol Processing of Materials" Wiley-VCH, New York, 1999 Mathiowitz, et al. "Biologically Erodable Microspheres as Potential Oral Drug Delivery Systems" Nature, Vol. 386, 1997, pgs. 410-414 DATE CONSIDERED EXAMINER EXAMINER: Initial if a citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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	(Rev. 2-88)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

5853-186US

APPLICANT

APPLICATION NO. 09/856,415

Sheet <u>4</u> of <u>4</u>

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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TALTON, et al.

GROUP 1615

(Use several sheets if necessary)						May 18, 2001				1615	
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